South Carolina
DHEC
Department of Health and Environmental Control
2600 Bull Street, Columbia, SC 29201

January 25, 1995

MEMORANDUM

TO: Nursing Home Administrators

FROM: Alan Samuels, Director
Division of Health Licensing

SUBJECT: Provider-wide partial exception to the isolation room and related air exchange requirements as outlined in Regulation 61-17, Standards for Licensing Nursing Homes

Requirements on the subject of negative pressure isolation rooms are found in Regulation 61-17, Standards for Licensing Nursing Homes, Sections X.(4)(a) and corresponding Table I, D.(3)(c)(1), D.(5)(c) & (d), and Y.(6)(f). Provisions of R61-17, Section X.(4)(a) and corresponding Table I, require that isolation rooms shall undergo a minimum of six (6) air changes per hour. We recognize that the rigid enforcement of this standard in existing nursing homes and proposed construction would work an extreme hardship on nursing homes and would not necessarily serve to promote the health and welfare of residents cared for in those facilities. In the interest of establishing reasonable standards which can be met by providers and yet do not compromise the health and welfare of residents cared for in South Carolina nursing homes we have determined that an alternative standard will be considered as acceptable.

All nursing homes will be required to meet either the standards outlined in R61-17, Sections X.(4)(a) and corresponding Table I, and Y.(6)(f), for negative pressure isolation rooms or, as an alternative:

1. A TB risk assessment shall be conducted in accordance with CDC guidelines as outlined on pp. 54249-54256 of the October 28, 1994 Federal Register (copy enclosed.) (NOTE: All facilities must conduct an annual risk assessment even if TB residents are not admitted.)

2. A written TB infection control plan shall be developed and implemented as described on p. 54255 of the October 28, 1994, Federal Register.

3. Risk assessments performed by individual facilities are expected to result in most nursing homes being categorized as very low risk facilities. Very low risk nursing homes will only be required to develop a written TB control plan including transfer policy (of sputum-positive pulmonary TB residents to an appropriate acute care facility.)

4. If risk assessment results indicate low, intermediate or high risk, a written TB control plan and a negative pressure room which meets R61-17, Section X.(4)(a) and corresponding Table I standards, will be required.

5. Nursing homes may accept residents with sputum-positive pulmonary TB and provide appropriate treatment in the nursing home, provided that CDC guidelines are met (such as negative pressure isolation rooms.) [Reference DHEC Regulation 61-17, Section D.(3)(c)(1).]

6. When nursing home residents with sputum-positive pulmonary TB are to remain in the nursing home for treatment instead of being transferred to another facility, appropriate isolation procedures will follow CDC guidelines, including those pertaining to negative pressure requirements. [Reference DHEC Regulation 61-17, Section D.(5)(c) & (d)].

7. Nursing homes which are determined to be "minimal risk" or "very low risk" are not required to have negative pressure isolation rooms. [Reference DHEC Regulation 61-17, Section X.(4)(a), especially Table I as it pertains to "setable" air pressure requirements for isolation rooms.]

QUESTIONS/CLARIFICATION ON THIS EXCEPTION

No application is required for the exception to be granted. Relevant citations will not be issued if this memorandum is followed. Providers should contact the Division of Health Licensing at DHEC [telephone number - (803)737-7202] on licensure questions; DHEC's TB Control Division [telephone number - (803) 737-4150] should be contacted for clarification of TB and/or CDC issues.

AS:DG:ms

Enclosure

cc: Douglas E. Bryant
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Bill Lafferty
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Karen Reeves

- Educating and training HCWs about TB, effective methods for preventing transmission of *M. tuberculosis*, and the benefits of medical screening programs (Section II.I).
- Developing and implementing a program for routine periodic counseling and screening of HCWs for active TB and latent TB infection (Section II.J; Suppl. 2).
- Promptly evaluating possible episodes of *M. tuberculosis* transmission in health-care facilities, including PPD skin-test conversions among HCWs, epidemiologically associated cases among HCWs or patients, and contacts of patients or HCWs who have TB and who were not promptly identified and isolated (Section II.K).
- Coordinating activities with the local public health department, emphasizing reporting, and ensuring adequate discharge follow-up and the continuation and completion of therapy (Section II.L).

II. Recommendations

A. Assignment of Responsibility

- Supervisory responsibility for the TB infection-control program should be assigned to a designated person or group of persons with expertise in infection control, occupational health, and engineering. These persons should be given the authority to implement and enforce TB infection-control policies.
- If supervisory responsibility is assigned to a committee, one person should be designated as the TB contact person. Questions and problems can then be addressed to this person.

B Risk Assessment, Development of the TB Infection-Control Plan, and Periodic Reassessment

1. Risk assessment

a. General

- TB infection-control measures for each health-care facility should be based on a careful assessment of the risk for transmission of *M. tuberculosis* in that particular setting. The first step in developing the TB infection-control program should be to conduct a baseline risk assessment to evaluate the risk for transmission of *M. tuberculosis* in each area and occupational group in the facility (Table 1, Figure 1). Appropriate infection-control interventions can then be developed on the basis of actual risk. Risk assessments should be performed for all inpatient and outpatient settings (e.g., medical and dental offices).
- Regardless of risk level, the management of patients with known or suspected infectious TB should not vary. However, the index of suspicion for infectious TB among patients, the frequency of HCW PPD skin testing, the number of TB isolation rooms, and other factors will depend on whether the risk for transmission of *M. tuberculosis* in the facility, area, or occupational group is high, intermediate, low, very low, or minimal.
- The risk assessment should be conducted by a qualified person or group of persons (e.g., hospital epidemiologists, infectious disease specialists, pulmonary disease specialists, infection-control practitioners, health-care administrators, occupational health personnel, engineers, HCWs, or local public health personnel).
- The risk assessment should be conducted for the entire facility and for specific areas within the facility (e.g., medical, TB, pulmonary, or HIV wards; HIV, infectious disease, or pulmonary clinics; and emergency departments or other areas where TB patients might receive

TABLE 1. Elements of a risk assessment for tuberculosis (TB) in health-care facilities

1. Review the community TB profile (from public health department data).
2. Review the number of TB patients who were treated in each area of the facility (both inpatient and outpatient). (This information can be obtained by analyzing laboratory surveillance data and by reviewing discharge diagnoses or medical and infection-control records.)
3. Review the drug-susceptibility patterns of TB isolates of patients who were treated at the facility.
4. Analyze purified protein derivative (PPD)-tuberculin skin-test results of health-care workers (HCWs), by area or by occupational group for HCWs not assigned to a specific area (e.g., respiratory therapists).
5. To evaluate infection-control parameters, review medical records of a sample of TB patients seen at the facility.

   Calculate intervals from:
   - admission until TB suspected;
   - admission until TB evaluation performed;
   - admission until acid-fast bacilli (AFB) specimens ordered;
   - AFB specimens ordered until AFB specimens collected;
   - AFB specimens collected until AFB smears performed and reported;
   - AFB specimens collected until cultures performed and reported;
   - AFB specimens collected until species identification conducted and reported;
   - AFB specimens collected until drug-susceptibility tests performed and reported;
   - admission until TB isolation initiated;
   - admission until TB treatment initiated; and
   - duration of TB isolation.

   Obtain the following additional information:
   - Were appropriate criteria used for discontinuing isolation?
   - Did the patient have a history of prior admission to the facility?
   - Was the TB treatment regimen adequate?
   - Were follow-up sputum specimens collected properly?
   - Was appropriate discharge planning conducted?

6. Perform an observational review of TB infection control practices.
7. Review the most recent environmental evaluation and maintenance procedures.

FIGURE 1. Protocol for conducting a tuberculosis (TB) risk assessment in a health-care facility

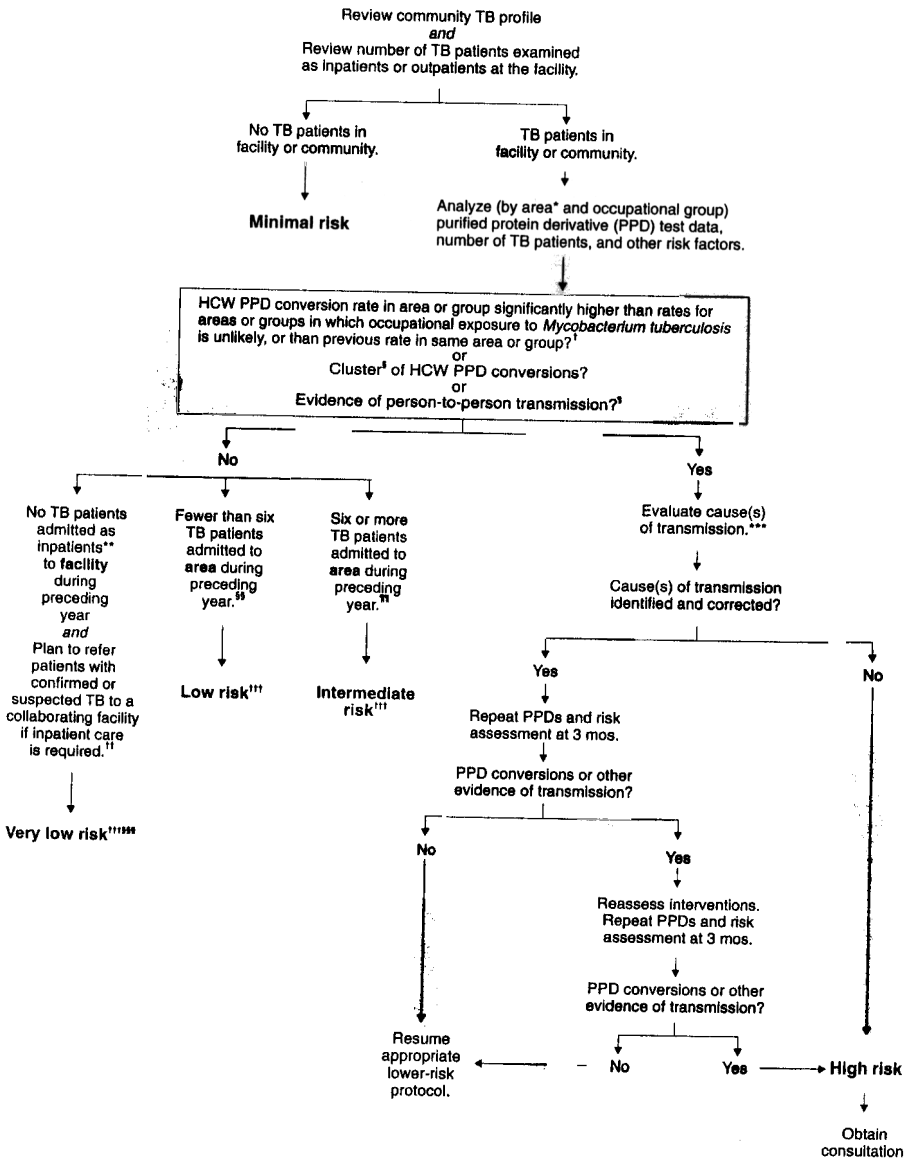

FIGURE 1. Protocol for conducting a TB risk assessment in a health-care facility — Continued

*Area: a structural unit (e.g., a hospital ward or laboratory) or functional unit (e.g., an internal medicine service) in which HCWs provide services to and share air with a specific patient population or work with clinical specimens that may contain viable *M. tuberculosis* organisms. The risk for exposure to *M. tuberculosis* in a given area depends on the prevalence of TB in the population served and the characteristics of the environment.

†With epidemiologic evaluation suggestive of occupational (nosocomial) transmission (see Problem Evaluation section in the text).

§Cluster: two or more PPD skin-test conversions occurring within a 3-month period among HCWs in a specific area or occupational group, and epidemiologic evidence suggests occupational (nosocomial) transmission.

¶For example, clusters of *M. tuberculosis* isolates with identical DNA fingerprint (RFLP) patterns or drug-resistance patterns, with epidemiologic evaluation suggestive of nosocomial transmission (see Problem Evaluation section in the text).

**Does not include patients identified in triage system and referred to a collaborating facility or patients being managed in outpatient areas.

††To prevent inappropriate management and potential loss to follow-up of patients identified in the triage system of a very low-risk facility as having suspected TB, an agreement should exist for referral between the referring and receiving facilities.

§§Or, for occupational groups, exposure to fewer than six TB patients for HCWs in the particular occupational group during the preceding year.

¶¶Or, for occupational groups, exposure to six or more TB patients for HCWs in the particular occupational group during the preceding year.

***See Problem Evaluation section in the text.

†††Occurrence of drug-resistant TB in the facility or community, or a relatively high prevalence of HIV infection among patients or HCWs in the area, may warrant a higher risk rating.

§§§For outpatient facilities, if TB cases have been documented in the community but no TB patients have been examined in the outpatient area during the preceding year, the area can be designated as very low risk.

care or where cough-inducing procedures are performed). This should include both inpatient and outpatient areas. In addition, risk assessments should be conducted for groups of HCWs who work throughout the facility rather than in a specific area (e.g., respiratory therapists; bronchoscopists; environmental services, dietary, and maintenance personnel; and students, interns, residents, and fellows).

- Classification of risk for a facility, for a specific area, and for a specific occupational group should be based on a) the profile of TB in the community; b) the number of infectious TB patients admitted to the area or ward, or the estimated number of infectious TB patients to whom HCWs in an occupational group may be exposed; and c) the results of analysis of HCW PPD test conversions (where applicable) and possible person-to-person transmission of *M. tuberculosis* (Figure 1).
- All TB infection-control programs should include periodic reassessments of risk. The frequency of repeat risk assessments should be based on the results of the most recent risk assessment (Table 2, Figure 1).
- The "minimal-risk" category applies only to an entire facility. A "minimal-risk" facility does not admit TB patients to inpatient or outpatient areas and is not located in a community with TB (i.e.,

TABLE 2. Elements of a tuberculosis (TB) infection-control program

Element	Risk categories				
	Minimal	Very low	Low	Intermediate	High
Assigning responsibility (Section II.A)					
Designated TB control officer or committee	R	R	R	R	R
Conducting a risk assessment (Section II.B.1)					
Baseline risk assessment	R	R	R	R	R
Community TB profile: incidence, prevalence, and drug-susceptibility patterns	Y	Y	Y	Y	Y
Facility case surveillance (laboratory- and discharge-diagnosis–based)	C	C	C	C	C
Analysis of purified protein derivative (PPD) test results among health-care workers (HCWs)	N/A	V*	Y	every 6–12 mos	every 3 mos
Review of TB patient medical records	N/A	O†	Y	every 6–12 mos	every 3 mos
Observation of infection-control practices	N/A	N/A	Y	every 6–12 mos	every 3 mos
Evaluation of engineering control maintenance	O§	O§	Y	every 6–12 mos	every 3 mos
Developing a TB infection control plan (Section II.B.2)					
Written TB infection control plan	R	R	R	R	R
Periodically reassessing risk (Section II.B.3)					
Reassessment of risk	Y	Y	Y	every 6–12 mos	every 3 mos
Identifying, evaluating, and initiating treatment for patients who may have active TB (Section II.C)					
Protocol (clinical prediction rules)¶ for identifying patients who may have active TB	R	R	R	R	R
Protocol for diagnostic evaluation of patients who may have active TB**	N/A	R	R	R	R

R=recommended; Y=yearly; C=continual; N/A=not applicable; O=optional; V=variable.

TABLE 2. Elements of a TB infection-control program — Continued

Element	Risk categories				
	Minimal	Very low	Low	Intermediate	High
Protocol for reporting laboratory results to clinicians, infection-control practitioners, collaborating referral facilities, and appropriate health department(s)	N/A	R	R	R	R
Protocol for initiating treatment of patients who may have active TB**	N/A	R	R	R	R
Managing patients who may have TB in ambulatory-care settings and emergency departments (Section II.D)					
Triage system for identifying patients who have active TB in emergency departments and ambulatory-care settings	R	R	R	R	R
Protocol for managing patients who may have active TB in emergency departments and ambulatory-care settings	R	R	R	R	R
Protocol for referring patients who may have active TB to collaborating facility	R	R	N/A††	N/A††	N/A††
Managing hospitalized patients who may have TB (Section II.E)					
Appropriate number of TB isolation rooms§§	N/A	N/A	R	R	R
Protocol for initiating TB isolation	N/A	N/A	R	R	R
Protocol for TB isolation practices	N/A	N/A	R	R	R
Protocol for discontinuing TB isolation	N/A	N/A	R	R	R
Protocol for discharge planning	N/A	N/A	R	R	R
Engineering controls (Suppl. 3, Section II.F)					
Protocol(s) for maintenance of engineering controls	O§	O§	R	R	R
Respiratory protection (Suppl. 4, Section II.G)					
Respiratory protection program	N/A	V*	R	R	R

TABLE 2. Elements of a TB infection-control program — Continued

Element	Risk categories				
	Minimal	Very low	Low	Intermediate	High
Cough-inducing and aerosol-generating procedures (Section II.H)					
Protocol(s) for performing cough-inducing or aerosol-generating procedures	O	O¶¶	R	R	R
Engineering controls for performing cough-inducing or aerosol-generating procedures	O§	O¶¶	R	R	R
Educating and Training HCWs (Section II.I)					
Educating and training HCWs regarding TB	R	R	R	R	R
Counseling and screening HCWs (Section II.J)					
Counseling HCWs regarding TB	R	R	R	R	R
Protocol for identifying and evaluating HCWs who have signs or symptoms of active TB	R	R	R	R	R
Baseline PPD testing of HCWs	O***	R	R	R	R
Routine periodic PPD screening of HCWs for latent TB infection	N/A	V*	Y	every 6–12 mos	every 3 mos
Protocol for evaluating and managing HCWs who have positive PPD tests	R	R	R	R	R
Protocol for managing HCWs who have active TB	R	R	R	R	R
Conducting a problem evaluation (Section II.K)					
Protocol for investigating PPD conversions and active TB in HCWs	R	R	R	R	R
Protocol for investigating possible patient-to-patient transmission of *Mycobacterium tuberculosis*	R	R	R	R	R

R=recommended; Y=yearly; C=continual; N/A=not applicable; O=optional; V=variable

TABLE 2. Elements of a TB infection-control program — Continued

Element	Risk categories				
	Minimal	Very low	Low	Intermediate	High
Protocol for investigating possible contacts of TB patients who were not diagnosed initially as having TB and were not placed in isolation	R	R	R	R	R
Coordination with the public health department (Section II.L)					
Effective system for reporting patients who have suspected or confirmed TB to appropriate health department(s)	R	R	R	R	

R=recommended; Y=yearly; C=continual; N/A=not applicable; O=optional; V=variable.

* Because very low-risk facilities do not admit patients who may have active TB to inpatient areas, most HCWs in such facilities do not need routine follow-up PPD screening after baseline PPD testing is done. However, those who are involved in the initial assessment and diagnostic evaluation of patients in the ambulatory-care, emergency, and admitting departments of such facilities or in the outpatient management of patients with active TB could be exposed potentially to a patient who has active TB. These HCWs may need to receive routine periodic PPD screening. Similarly, these HCWs may need to be included in a respiratory protection program.

† Because very low-risk facilities do not admit patients suspected of having active TB, review of TB patient medical records is not applicable. However, follow-up of patients who were identified during triage as possibly having active TB and referred to another institution for further evaluation and management may be useful in evaluating the effectiveness of the triage system.

§ Some minimal or very low-risk facilities may elect to use engineering controls (e.g., booths for cough-inducing procedures, portable high-efficiency particulate [HEPA] filtration units, ultraviolet germicidal irradiation units) in triage/waiting areas. In such situations, appropriate protocols for maintaining this equipment should be in place, and this maintenance should be evaluated periodically.

¶ The criteria used in clinical prediction rules will probably vary from facility to facility depending on the prevalence of TB in the population served by the facility and on the clinical, radiographic, and laboratory characteristics of TB patients examined in the facility.

** The protocols should be consistent with CDC/American Thoracic Society recommendations (*33*).

†† Protocols for referring patients who require specialized treatment (e.g., patients with multidrug-resistant TB) may be appropriate.

§§ Based on maximum daily number of patients requiring TB isolation for suspected or confirmed active TB. Isolation rooms should meet the performance criteria specified in these guidelines.

¶¶ If such procedures are used in the triage protocol(s) for identifying patients who may have active TB.

*** Minimal-risk facilities do not need to maintain an ongoing PPD skin-testing program. However, baseline PPD testing of HCWs may be advisable so that if an unexpected exposure does occur, conversions can be distinguished from positive PPD test results caused by previous exposures.

counties or communities in which TB cases have not been reported during the previous year). Thus, there is essentially no risk for exposure to TB patients in the facility. This category may also apply to many outpatient settings (e.g., many medical and dental offices).

- The "very low-risk" category generally applies only to an entire facility. A very low-risk facility is one in which a) patients with active TB are not admitted to inpatient areas but may receive initial assessment and diagnostic evaluation or outpatient management in outpatient areas (e.g., ambulatory-care and emergency departments) and b) patients who may have active TB and need inpatient care are promptly referred to a collaborating facility. In such facilities, the outpatient areas in which exposure to patients with active TB could occur should be assessed and assigned to the appropriate low-, intermediate-, or high-risk category. Categorical assignment will depend on the number of TB patients examined in the area during the preceding year and whether there is evidence of nosocomial transmission of *M. tuberculosis* in the area. If TB cases have been reported in the community, but no patients with active TB have been examined in the outpatient area during the preceding year, the area can be designated as very low risk (e.g., many medical offices).

  The referring and receiving facilities should establish a referral agreement to prevent inappropriate management and potential loss to follow-up of patients suspected of having TB during evaluation in the triage system of a very low-risk facility.

  In some facilities in which TB patients are admitted to inpatient areas, a very low-risk protocol may be appropriate for areas (e.g., administrative areas) or occupational groups that have only a very remote possibility of exposure to *M. tuberculosis*.

  The very low-risk category may also be appropriate for outpatient facilities that do not provide initial assessment of persons who may have TB, but do screen patients for active TB as part of a limited medical screening before undertaking specialty care (e.g., dental settings).

- "Low-risk" areas or occupational groups are those in which a) the PPD test conversion rate is not greater than that for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, b) no clusters* of PPD test conversions have occurred, c) person-to-person transmission of *M. tuberculosis* has not been detected, and d) fewer than six TB patients are examined or treated per year.

- "Intermediate-risk" areas or occupational groups are those in which a) the PPD test conversion rate is not greater than that for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, b) no clusters of PPD test conversions have occurred, c) person-to-person transmission of *M. tuberculosis* has not been detected, and d) six or more patients with active TB are examined or treated each year. Survey data suggest that facilities in which six or more TB patients are examined or treated each year may have an increased risk for transmission of *M. tuberculosis* (CDC, unpublished data); thus, areas in which six or more patients with active TB are examined or treated each year (or occupational groups in which HCWs are likely to be exposed to six or more TB patients per year) should be classified as "intermediate risk."

- "High-risk" areas or occupational groups are those in which a) the PPD test conversion rate is significantly greater than for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely or than previous conversion rates for the same area or group, and epidemiologic evaluation suggests nosocomial transmission; **or** b) a cluster of PPD test conversions has occurred, and epidemiologic evaluation suggests nosocomial transmission of *M. tuberculosis*; **or** c) possible person-to-person transmission of *M. tuberculosis* has been detected.

- If no data or insufficient data for adequate determination of risk have been collected, such data should be compiled, analyzed, and reviewed expeditiously.

b. Community TB profile

- A profile of TB in the community that is served by the facility should be obtained from the public health department. This profile should include, at a minimum, the incidence (and prevalence, if available) of active TB in the community and the drug-susceptibility patterns of *M. tuberculosis* isolates (i.e., the antituberculous agents to which each isolate is susceptible and those to which it is resistant) from patients in the community.

c. Case surveillance

- Data concerning the number of suspected and confirmed active TB cases among patients and HCWs in the facility should be systematically collected, reviewed, and used to estimate the number of TB isolation rooms needed, to recognize possible clusters of nosocomial transmission, and to assess the level of potential occupational risk. The number of TB patients in specific areas of a facility can be obtained from laboratory surveillance data on specimens positive for AFB smears or *M. tuberculosis* cultures, from infection-control records, and from databases containing information about hospital discharge diagnoses.

- Drug-susceptibility patterns of *M. tuberculosis* isolates from TB patients treated in the facility should be reviewed to identify the frequency and patterns of drug resistance. This information may indicate a need to modify the initial treatment regimen or may suggest possible nosocomial transmission or increased occupational risk.

d. Analysis of HCW PPD test screening data

- Results of HCW PPD testing should be recorded in the individual HCW's employee health record and in a retrievable aggregate data-

*Cluster: two or more PPD skin-test conversions occurring within a 3-month period among HCWs in a specific area or occupational group, and epidemiologic evidence suggests occupational (nosocomial) transmission.

base of all HCW PPD test results. Personal identifying information should be handled confidentially. PPD test conversion rates should be calculated at appropriate intervals to estimate the risk for PPD test conversions for each area of the facility and for each specific occupational group not assigned to a specific area (Table 2). To calculate PPD test conversion rates, the total number of previously PPD-negative HCWs tested in each area or group (i.e., the denominator) and the number of PPD test conversions among HCWs in each area or group (the numerator) must be obtained.

- PPD test conversion rates for each area or occupational group should be compared with rates for areas or groups in which occupational exposure to *M. tuberculosis* is unlikely and with previous conversion rates in the same area or group to identify areas or groups where the risk for occupational PPD test conversions may be increased. A low number of HCWs in a specific area may result in a greatly increased rate of conversion for that area, although the actual risk may not be significantly greater than that for other areas. Testing for statistical significance (e.g., Fisher's exact test or chi square test) may assist interpretation; however, lack of statistical significance may not rule out a problem (i.e., if the number of HCWs tested is low, there may not be adequate statistical power to detect a significant difference). Thus, interpretation of individual situations is necessary.
- An epidemiologic investigation to evaluate the likelihood of nosocomial transmission should be conducted if PPD test conversions are noted (Section II.K.1).
- The frequency and comprehensiveness of the HCW PPD testing program should be evaluated periodically to ensure that all HCWs who should be included in the program are being tested at appropriate intervals. For surveillance purposes, earlier detection of transmission may be enhanced if HCWs in a given area or occupational group are tested on different scheduled dates rather than all being tested on the same date (Section II.J.3).

e. Review of TB patient medical records

- The medical records of a sample of TB patients examined at the facility can be reviewed periodically to evaluate infection-control parameters (Table 1). Parameters to examine may include the intervals from date of admission until a) TB was suspected, b) specimens for AFB smears were ordered, c) these specimens were collected, d) tests were performed, and e) results were reported. Moreover, the adequacy of the TB treatment regimens that were used should be evaluated.
- Medical record reviews should note previous hospital admissions of TB patients before the onset of TB symptoms. Patient-to-patient transmission may be suspected if active TB occurs in a patient who had a prior hospitalization during which exposure to another TB patient occurred or if isolates from two or more TB patients have identical characteristic drug-susceptibility or DNA fingerprint patterns.
- Data from the case review should be used to determine if there is a need to modify a) protocols for identifying and isolating patients who may have infectious TB, b) laboratory procedures, c) administrative policies and practices, or d) protocols for patient management.

f. Observation of TB infection-control practices

- Assessing adherence to the policies of the TB infection-control program should be part of the evaluation process. This assessment should be performed on a regular basis and whenever an increase occurs in the number of TB patients or HCW PPD test conversions. Areas at high risk for transmission of *M. tuberculosis* should be monitored more frequently than other areas. The review of patient medical records provides information on HCW adherence to some of the policies of the TB infection-control program. In addition, work practices related to TB isolation (e.g., keeping doors to isolation rooms closed) should be observed to determine if employers are enforcing, and HCWs are adhering to, these policies and if patient adherence is being enforced. If these policies are not being enforced or adhered to, appropriate education and other corrective action should be implemented.

g. Engineering evaluation

- Results of engineering maintenance measures should be reviewed at regular intervals (Table 3). Data from the most recent evaluation and from maintenance procedures and logs should be reviewed carefully as part of the risk assessment.

2. Development of the TB Infection-Control Plan

- Based on the results of the risk assessment, a written TB infection-control plan should be developed and implemented for each area of the facility and for each occupational group of HCWs not assigned to a specific area of the facility (Table 2; Table 3).
- The occurrence of drug-resistant TB in the facility or the community, or a relatively high prevalence of HIV infection among patients or HCWs in the community, may increase the concern about transmission of *M. tuberculosis* and may influence the decision regarding which protocol to follow (i.e., a higher-risk classification may be selected).
- Health-care facilities are likely to have a combination of low-, intermediate-, and high-risk areas or occupational groups during the same time period. The appropriate protocol should be implemented for each area or group.
- Areas in which cough-inducing procedures are performed on patients who may have active TB should, at the minimum, implement the intermediate-risk protocol.

3. Periodic Reassessment

- Follow-up risk assessment should be performed at the interval indicated by the most recent risk assessment (Figure 1; Table 2). Based on

TABLE 3. Characteristics of an effective tuberculosis (TB) infection-control program*

I. Assignment of responsibility
- A. Assign responsibility for the TB infection-control program to qualified person(s).
- B. Ensure that persons with expertise in infection control, occupational health, and engineering are identified and included.

II. Risk assessment, TB infection-control plan, and periodic reassessment
- A. Initial risk assessments
  1. Obtain information concerning TB in the community.
  2. Evaluate data concerning TB patients in the facility.
  3. Evaluate data concerning purified protein derivative (PPD)-tuberculin skin-test conversions among health-care workers (HCWs) in the facility.
  4. Rule out evidence of person-to-person transmission.
- B. Written TB infection-control program
  1. Select initial risk protocol(s).
  2. Develop written TB infection-control protocols.
- C. Repeat risk assessment at appropriate intervals.
  1. Review current community and facility surveillance data and PPD-tuberculin skin-test results.
  2. Review records of TB patients.
  3. Observe HCW infection-control practices.
  4. Evaluate maintenance of engineering controls.

III. Identification, evaluation, and treatment of patients who have TB
- A. Screen patients for signs and symptoms of active TB:
  1. On initial encounter in emergency department or ambulatory-care setting.
  2. Before or at the time of admission.
- B. Perform radiologic and bacteriologic evaluation of patients who have signs and symptoms suggestive of TB.
- C. Promptly initiate treatment.

IV. Managing outpatients who have possible infectious TB
- A. Promptly initiate TB precautions.
- B. Place patients in separate waiting areas or TB isolation rooms.
- C. Give patients a surgical mask, a box of tissues, and instructions regarding the use of these items.

V. Managing inpatients who have possible infectious TB
- A. Promptly isolate patients who have suspected or known infectious TB.
- B. Monitor the response to treatment.
- C. Follow appropriate criteria for discontinuing isolation.

VI. Engineering recommendations
- A. Design local exhaust and general ventilation in collaboration with persons who have expertise in ventilation engineering.
- B. Use a single-pass air system or air recirculation after high-efficiency particulate air (HEPA) filtration in areas where infectious TB patients receive care.
- C. Use additional measures, if needed, in areas where TB patients may receive care.

*A program such as this is appropriate for health-care facilities in which there is a high risk for transmission of *Mycobacterium tuberculosis.*

TABLE 3. Characteristics of an effective TB infection-control program — Continued

- D. Design TB isolation rooms in health-care facilities to achieve ≥6 air changes per hour (ACH) for existing facilities and ≥12 ACH for new or renovated facilities.
- E. Regularly monitor and maintain engineering controls.
- F. TB isolation rooms that are being used should be monitored daily to ensure they maintain negative pressure relative to the hallway and all surrounding areas.
- G. Exhaust TB isolation room air to outside or, if absolutely unavoidable, recirculate after HEPA filtration.

VII. Respiratory protection
- A. Respiratory protective devices should meet recommended performance criteria.
- B. Repiratory protection should be used by persons entering rooms in which patients with known or suspected infectious TB are being isolated, by HCWs when performing cough-inducing or aerosol-generating procedures on such patients, and by persons in other settings where administrative and engineering controls are not likely to protect them from inhaling infectious airborne droplet nuclei.
- C. A respiratory protection program is required at all facilities in which respiratory protection is used.

VIII. Cough-inducing procedures
- A. Do not perform such procedures on TB patients unless absolutely necessary.
- B. Perform such procedures in areas that have local exhaust ventilation devices (e.g., booths or special enclosures) or, if this is not feasible, in a room that meets the ventilation requirements for TB isolation.
- C. After completion of procedures, TB patients should remain in the booth or special enclosure until their coughing subsides.

IX. HCW TB training and education
- A. All HCWs should receive periodic TB education appropriate for their work responsibilities and duties.
- B. Training should include the epidemiology of TB in the facility.
- C. TB education should emphasize concepts of the pathogenesis of and occupational risk for TB.
- D. Training should describe work practices that reduce the likelihood of transmitting *M. tuberculosis.*

X. HCW counseling and screening
- A. Counsel all HCWs regarding TB and TB infection.
- B. Counsel all HCWs about the increased risk to immunocompromised persons for developing active TB.
- C. Perform PPD skin tests on HCWs at the beginning of their employment, and repeat PPD tests at periodic intervals.
- D. Evaluate symptomatic HCWs for active TB.

XI. Evaluate HCW PPD test conversions and possible nosocomial transmission of *M. tuberculosis.*

XII. Coordinate efforts with public health department(s)

the results of the follow-up assessment, problem evaluation may need to be conducted or the protocol may need to be modified to a higher- or lower-risk level.

- After each risk assessment, the staff responsible for TB control, in conjunction with other appropriate HCWs, should review all TB control policies to ensure that they are effective and meet current needs.

4. Examples of Risk Assessment

Examples of six hypothetical situations and the means by which surveillance data are used to select a TB control protocol are described as follows:

Hospital A. The overall HCW PPD test conversion rate in the facility is 1.6%. No areas or HCW occupational groups have a significantly greater PPD test conversion rate than areas or groups in which occupational exposure to *M. tuberculosis* is unlikely (or than previous rates for the same area or group). No clusters of PPD test conversions have occurred. Patient-to-patient transmission has not been detected. Patients who have TB are admitted to the facility, but no area admits six or more TB patients per year. The low-risk protocol will be followed in all areas.

Hospital B. The overall HCW PPD test conversion rate in the facility is 1.8%. The PPD test conversion rate for the medical intensive-care unit rate is significantly higher than all other areas in the facility. The problem identification process is initiated (Section II.K). It is determined that all TB patients have been isolated appropriately. Other potential problems are then evaluated, and the cause for the higher rate is not identified. After consulting the public health department TB infection-control program, the high-risk protocol is followed in the unit until the PPD test conversion rate is similar to areas of the facility in which occupational exposure to TB patients is unlikely. If the rate remains significantly higher than other areas, further evaluation, including environmental and procedural studies, will be performed to identify possible reasons for the high conversion rate.

Hospital C. The overall HCW PPD test conversion rate in the facility is 2.4%. Rates range from 0 to 2.6% for the individual areas and occupational groups. None of these rates is significantly higher than rates for areas in which occupational exposure to *M. tuberculosis* is unlikely. No particular HCW group has higher conversion rates than the other groups. No clusters of HCW PPD test conversions have occurred. In two of the areas, HCWs cared for more than six TB patients during the preceding year. These two areas will follow the intermediate-risk protocol, and all other areas will follow the low-risk protocol. This hospital is located in the southeastern United States, and these conversion rates may reflect cross-reactivity with nontuberculous mycobacteria.

Hospital D. The overall HCW PPD test conversion rate in the facility is 1.2%. In no area did HCWs care for six or more TB patients during the preceding year. Three of the 20 respiratory therapists tested had PPD conversions, for a rate of 15%. The respiratory therapists who had PPD test conversions had spent all or part of their time in the pulmonary function laboratory, where induced sputum specimens were obtained. A low-risk protocol is maintained for all areas and occupational groups in the facility except for respiratory therapists. A problem evaluation is conducted in the pulmonary function laboratory (Section II.K). It is determined that the ventilation in this area is inadequate. Booths are installed for sputum induction. PPD testing and the risk assessment are repeated 3 months later. If the repeat testing at 3 months indicates that no more conversions have occurred, the respiratory therapists will return to the low-risk protocol.

Hospital E. Hospital E is located in a community that has a relatively low incidence of TB. To optimize TB services in the community, the four hospitals in the community have developed an agreement that one of them (e.g., Hospital G) will provide all inpatient services to persons who have suspected or confirmed TB. The other hospitals have implemented protocols in their ambulatory-care clinics and emergency departments to identify patients who may have active TB. These patients are then transferred to Hospital G for inpatient care if such care is considered necessary. After discharge from Hospital G, they receive follow-up care in the public health department's TB clinic. During the preceding year, Hospital E has identified fewer than six TB patients in its ambulatory-care and emergency departments and has had no PPD test conversions or other evidence of *M. tuberculosis* transmission among HCWs or patients in these areas. These areas are classified as low risk, and all other areas are classified as very low risk.

Hospital F. Hospital F is located in a county in which no TB cases have been reported during the preceding 2 years. A risk assessment conducted at the facility did not identify any patients who had suspected or confirmed TB during the preceding year. The facility is classified as minimal risk.

C Identifying, Evaluating, and Initiating Treatment for Patients Who May Have Active TB

The most important factors in preventing transmission of *M. tuberculosis* are the early identification of patients who may have infectious TB, prompt implementation of TB precautions for such patients, and prompt initiation of effective treatment for those who are likely to have TB.

1. Identifying patients who may have active TB

- Health-care personnel who are assigned responsibility for TB infection control in ambulatory-care and inpatient settings should develop, implement, and enforce protocols for the early identification of patients who may have infectious TB.